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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,452	REITER ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *15-18,20,22-26 and 43-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,19,21 and 27-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *15-18,20,22-26 and 43-54* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/22/04; 9/23/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 2pgs.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/29/02; 5/5/05; 7/18/05 3 pgs
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-14, 19, 21 and 27-42 (species election of *H. pylori* as acid-resistant microorganism, catalase as antigen, SEQ ID NO: 21-23 heavy chain, SEQ ID NO: 27-29 light chain and SEQ ID NO: 1 variable regions in the reply filed on May 3, 2005 is acknowledged. The traversal is on the grounds that Larka et al neither discloses the method of detection of the present invention nor the antibodies to *H. pylori* antigen as claimed. In essence, the inventors of thee claimed invention started from the teaching of Larka et al and found a new principle for determining acid-resistant microorganism like *H. pylori* in feces by using a different type of receptor in the test, i.e., as defined in claim 1, a receptor that specifically binds an antigen which is found after passage through the intestine. The inventors of the claimed invention found that it is possible to reliably detect infection caused by an acid-resistant-microorganism if one or two specific receptors as identified in claim 1 are used. These specific receptors bind an antigen, which shows a structure after the passage through the intestine that corresponds to the native structure or the structure, which a mammal produces antibodies against after being infected or immunized. Since the prior art never contemplated selecting those receptors binding with antigens in feces and that the method using such receptors as well novel and inventive. However, it would appear that if the sample is a stool sample then the antigen is one found in stool after passage through the intestine and the receptors/antibodies disclosed in Larka et al were able to detect infection in a mammal with an acid-resistant microorganism. Applicants have asserted that the disclosure of Larka et al does not contemplate the use of

"one receptor" but instead expressly requires polyclonal antibodies, in other words a multiplicity of different receptors. However, the claims are directed to polyclonal antibodies and claim 1 also recites "(ab) two different receptors", which would appear to be multiple receptors. Applicants have asserted that quantitative determinations and predetermined numbers of organisms taught in Larka et al would not be very encouraging and would not be useful in the detection methods. However, the claims do not define a specific level of activity that defines a negative result. As previously stated the pending claims contemplate the use of multiple receptors/antibodies which would appear to be the same or similar to the prior art of Larka et al.

For the reasons discussed above Applicants' arguments have not been deemed persuasive and the requirement is still deemed proper and is therefore made FINAL.

2. Claims 15-18, 20, 22-26 and 43-54 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 3, 2005.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.The oath or declaration is defective because: It does not identify the city and either state or foreign country of residence of each inventor. The residence

information may be provided on either on an application data sheet or supplemental oath or declaration.
It was not executed in accordance with either 37 CFR 1.66 or 1.68. There is no date recited when the inventors signed the oath.

4. Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on an application filed in as a 371 of PCT/EP00/10058 10/12/2000, EUROPEAN PATENT OFFICE (EPO) 99120351.4 10/12/1999, EUROPEAN PATENT OFFICE (EPO) 00105592.0 03/16/2000, EUROPEAN PATENT OFFICE (EPO) 00107028.3 03/31/2000 and EUROPEAN PATENT OFFICE (EPO) 00110110.4 05/10/2000. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign applications. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

5. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

6. Because Applicants have not perfected the priority documents with regard to filing certified copies of the English translations of these priority documents, the effective filing date is the filing date of the pending application, January 27, 2003. All of the priority documents are in German.

7. Claims 1-14, 19, 21 and 27-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 5 and those claims that depend from claim 5 are vague and indefinite in the recitation for "preferably". A generic phrase followed by a more specific phrase causes a claim to be broad and narrow simultaneously; it is not clear what is intended. Claims 19 and 21 are vague and indefinite in the recitation for "preferably" and "more preferably". A generic phrase followed by a more specific phrase causes a claim to be broad and narrow simultaneously; it is not clear what is intended. Claim 29 is vague and indefinite in the recitation for "preferably" and "particularly preferably". A generic phrase followed by a more specific phrase causes a claim to be broad and narrow simultaneously; it is not clear what is intended. Claim 19 lacks positive antecedent basis in the recitation of "or test". Claim 35 is vague and indefinite in the recitation of "method is a one step ELISA". Does this refer to the detection recited in part (b) of claim 1 or the method recited in the first line of claim 1? Claim 36 is vague and indefinite in the recitation of "method is a three step ELISA". Does this refer to the detection recited in part (b) of claim 1 or the method recited in the first line of claim 1? Claim 41 is vague and indefinite in the recitation of "method is a automated method". Does this refer to the detection recited in part (b) of claim 1 or the method recited in the first line of claim 1? Claim 32 lacks positive antecedent basis in the recitation of "in RIA or in ELISA". Claim 11 is vague and indefinite in the recitation of "lysate if a lysate with depleted immunodominant antigens". If claim 9 from which claim 10 depends

recites that the lysate is a lysate with enriched antigens, how can the dependent claim be depleted of immunodominant antigens? It is not clear what Applicants intend. Claim 12 is vague and indefinite in the recitation of "polyclonal antiserum is obtained against a purified or (semi-) synthetically produced antigen". It is not clear as to what Applicant intends since synthetic proteins or peptides do not produce antibodies directly. The claims are vague and indefinite in the recitation of "synthetic peptide produces antibodies". It is not clear as to what Applicant intends since synthetic proteins or peptides do not produce antibodies directly. Claim 6 is vague and indefinite in the recitation of "derivative(s) thereof". What does Applicant intend? What amount (metes and bounds) of modification is permitted for a derivative to still be considered a derivative?

8. Claims 7, 14 and 36 are objected to because of the following informalities: claim 7 recites "according to of claim", please correct. Claim 14 recites "according claim"; this should be "according to claim". There should be a period at the end of claim 36. Applicants should review all claim language. Appropriate correction is required.

9. Claim 40 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 40 recites that "breath condensate, gastric gases, tooth plaque, saliva, mucous smear, biopsy, whole blood or serum is used for the detection instead of a stool sample". Removing a limitation from

the independent claim, does not further limit that claim. Appropriate correction is required.

10. The disclosure is objected to because of the following informalities: Paragraph [0112] on page 22 recites an amino acid sequence, which is not identified by a sequence identifier. The sequences in Table 10 on pages 54-55 do not have sequence identifiers. Appropriate correction is required.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-14, 19, 21 and 27-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 46-50, 54-63 and 69 of copending Application No. 10/110410. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim methods for detecting an infection of a mammal with an acid-resistant microorganism (can be acid-resistant bacterium), comprising incubating a stool sample with a receptor and permitting the complex to form and then detecting the antigen-receptor complex.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure for the claimed invention. The specification teaches various monoclonal antibodies, specifically HP25.6m/1B5 and HP25.2m/2H10, both related to catalase. It appears that these monoclonal antibodies are necessary to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, a deposit of the above plasmid may satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See 37 C.F.R. 1.802.

It is noted that the some monoclonal antibodies (those for urease) have been deposited. However, the certificate of deposit has not been provided nor have the statements of assurance been made, see below. If a

deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If the deposits have not been made under the provisions of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository (with address) and that the following criteria have been met:

(a) during the tendency of the application, access to the deposits will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

© the deposits will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

14. Claims 1-14, 19, 21 and 27-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the above objection to the specification.

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

16. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the

reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

17. Claims 1-4, 6, 14 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Reiter et al (WO 00/26671 A1).

Reiter et al discloses a "method for detecting an infection of a mammal with an acid-resistant micro-organism, comprising the following steps: a) incubating a stool sample of the mammal with at least two different monoclonal antibodies, fragments or derivatives thereof or aptamers in conditions which allow the formation of a complex of antigens from the micro-organism and the antibodies, (aa) the first monoclonal antibody specifically binding an epitope of the first antigen, (ab) the second monoclonal antibody specifically binding a different epitope to the epitope of the first antigen, of a second antigen, and the proportions of the mammals according to (aa) and according to (ab) being able to overlap, and in total, essentially making up the total number of infected mammals; and (b) detecting the formation of at least one antigen-antibody complex or antigen-aptamer complex according to (aa) or (ab)." (abstract).

The prior art anticipates the claimed invention. Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the

prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

18. Claims 1, 2, 6-12, 14, 29-39, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Svenson et al (WO 97/34149) or Mandrell et al (WO 99/49889).

Svenson et al discloses a method for detecting an infection (mycobacterial disease) in a mammal with an acid-resistant microorganism (Mycobacterium) comprising incubating a feces sample (stool sample), and that polyclonal antibodies or monoclonal antibodies directed against the mycobacterial antigen were used in an assay detecting the complexes formed (abstract; p. 3; p. 7; claims). ELISA and RIAs were used as a means of detection (p. 2; claims).

Mandrell et al discloses methods for testing for infection in a mammal with an acid-resistant microorganism using antibodies to detect the acid-resistant microorganism (p. 12). "The method of testing is described further wherein the sample is selected from the group consisting of poultry, swine and bovine carcasses, tissues and manure; animal production (farm) or processing water and equipment; biofilms on surfaces of animal carcasses, cells, tissues, production equipment or processing equipment; clinical samples (for example, feces or blood); fruit and vegetables; and fruit and vegetable irrigation and processing water." (p. 13) Mandrell et al discloses the use of polyclonal and monoclonal antibodies directed against proteins/antigens from acid-resistant microorganisms (claims).

The prior art anticipates the claimed invention. Since the Patent Office does not have the facilities for examining and comparing applicants'

methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

19. Claims 1-14, 29-35, 37-39 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Nakaya et al (WO 02/088737 A1, Abstract Only).

Nakaya et al discloses a method for detecting an infection of a mammal with an acid-resistant microorganism, comprising the following steps: a) incubating a stool sample (feces is test sample) of the mammal with antibodies (abstract). Nakaya et al discloses immobilizing the antibody to a nitrocellulose sheet on which the monoclonal antibody capable of undergoing an antigen-antibody reaction with catalase of *H. pylori* (abstract).

The prior art anticipates the claimed invention. Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

20. Claims 1-4, 6-12, 14, 30-33, 35, 37, 38, 40 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al (Lancet, 1992, 340:1194-1195).

Thomas et al discloses obtaining stool samples from mammals (humans) for detecting H. pylori infection (acid-resistant microorganism, bacterium) in the mammal (p. 1194). The faecal sample was suspended in PBS (p. 1194). The antigen-antibody complex was detected by ELISA (p. 1194).

The prior art anticipates the claimed invention. Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

21. Claims 1-4, 6-12, 14, 29-39, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Larka et al (5932430).

Larka et al discloses a process for the determination of *H. pylori* (acid-resistant microorganism, bacterium) infection in a fecal specimen (stool sample) comprising contacting the sample with a diluent that has an antibody for *H. pylori* to form an antigen-antibody complex and then detecting the complex that has been formed (abstract; col. 2; claims). Larka et al discloses the use of both polyclonal, monoclonal antibodies as well as a plurality of antibodies, which generically refers to a polyclonal antibody and a mixture of monoclonal antibodies (col. 2). Larka et al

discloses that the antibodies (receptors) can be immobilized (fixed) to a support such as filter paper, plastic beads and the like (col. 3). ELISA was used to monitor the complex formed (example 4, col. 6; col. 8).

The prior art anticipates the claimed invention. Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

22. No claims are allowed.

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)..

N M. Minnifield
Primary Examiner
Art Unit 1645

NMM
August 22, 2005